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14. 510(K) SUMMARY OR 510(K) STATEMENT

Ellipse Intramedullary Limb Lengthening System
510(k) Summary – K101997
June 2010

1. **Company:** Ellipse Technologies, Incorporated
13844 Alton Parkway, Suite 130
Irvine, CA 92618

Contact: John McIntyre
Vice President, RA/QA/CA

2. **Proprietary Trade Name:** Ellipse Intramedullary Limb Lengthening System

3. **Classification Name: 21 CFR 888.3020 --** Intramedullary fixation rod

4. **Product Code:** HSB – Rod, Fixation, Intramedullary and Accessories

5. **Product Description:**

The Ellipse Intramedullary Limb Lengthening System is composed of a modular implantable intramedullary rod ("Distracting Rod"), locking screws, an external remote controller (ERC), and implantation tools and accessories. The modular implantable rod is available in different configurations, lengths, and diameters to accommodate a variety of patient anatomies. Likewise, the locking screws are available in two different diameters and a variety of lengths from 20 mm to 75 mm in 5 mm increments. The distracting rod is a modular system that includes the IMLL Actuator component and various configurations of IMLL Extension Rods. The IMLL Actuator includes an enclosed rare earth magnet, telescoping lead screw/nut assembly and gearing. The IMLL Actuator is supplied sterile by gamma sterilization while the IMLL Extension Rods, locking screws, and reusable accessories are supplied non-sterile and must be sterilized prior to use.

6. **Indications**

The Ellipse Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femurs.

7. Substantial equivalence

Documentation that includes mechanical test results and detailed comparison to the predicate device demonstrates that the Ellipse Intramedullary Limb Lengthening System is substantially equivalent to the Orthodyne/Orthofix ISKD device (K010322 and K031219).

Substantial equivalence is based on similar indications for use, designs, and on *in vitro* testing performed.

The Ellipse IMLL System and the predicate device have similar technological characteristics. Specifically, the Ellipse IMLL System and the predicate devices are both designed to be implanted into the medullary canal of the femur or tibia. These devices are available in a variety of geometrical configurations and diameters/lengths to accommodate a variety of patient anatomies. Both devices are designed as a telescoping rod that can be lengthened non-invasively. The ISKD device is lengthened by manual mechanical rotation of the limb while the Ellipse IMLL system is lengthened by the interaction of the rare earth magnet which is contained within the actuator portion of the rod and the external remote controller. The Ellipse IMLL system has the advantage that the length of the rod can be shortened if the rod has been distracted too much. The ISKD device can only be adjusted in one direction (i.e., distraction).

Furthermore, the Ellipse IMLL and the ISKD device have a number of common design features, such as a telescoping Titanium alloy rod that is attached proximally and distally using locking screws. Both devices have telescoping features that are adjustable non-invasively. The Ellipse IMLL gives the user a better level of control of the distraction amount and direction, however.

The Ellipse IMLL device and the predicate device feature similar overall shapes. The various configurations and dimensions are available to accommodate the variety of patient anatomies encountered in limb lengthening procedures.

Testing included sterilization validation, shelf life testing for the packaging and the device functionality, biocompatibility testing, and testing to ASTM F1264-03 for intramedullary rods and F543-07 for metallic medical bone screws. Additional testing to demonstrate the safety of the magnetic fields from both the rare earth magnet included in the IMLL Actuator as well as the External Remote Controller demonstrated that the induced magnetic fields are below established

safety guidelines. Testing on the external remote controller also included software verification and validations, electrical safety testing, and electromagnetic interference and compatibility testing. The following specific tests have been performed in order to establish equivalence to the predicate device:

Test Description	Applicable test standard
VD_{max}^{25} Gamma Radiation Sterilization Validation	ANSI/AAMI/ISO 11137-2: 2007
6 month shelf life packaging validation	ISO 11607
Biocompatibility testing	ISO 10993-1: 2003
External remote controller software validation testing	IEC 60601-1-4
External remote controller electrical safety testing	IEC 60601-1
External remote controller electromagnetic interference and compatibility testing	IEC 60601-1-2
Locking screw Static and dynamic three point bend testing	ASTM F1264-03
Locking screw axial pullout testing	ASTM F543-07
Locking screw torque to failure	ASTM F543-07
Implantable rod static and dynamic 4-point bend testing	ASTM F1264-03
Implantable rod torque to failure	ASTM F543-07
Implantable rod torsional stiffness	ASTM F1264-03
Fixture and device compliance	ASTM F1264-03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2011

Ellipse Technologies, Inc.
% Mr. John McIntyre
Vice President, Regulatory, Quality
and Clinical Affairs
13844 Alton Parkway, Suite 130
Irvine, California 92618

Re: K101997
Trade Name: Ellipse Intramedullary Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: March 25, 2011
Received: March 28, 2011

Dear Mr. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~Unknown~~ K101997

Device Name: Ellipse Intramedullary Limb Lengthening System

Indications for Use: The Ellipse Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femurs.

Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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